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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	12

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,161	RALPH, PETER	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-448* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-19 and 46 in the reply filed on October 27, 2003 is acknowledged and entered into record.

Claims 49-62 are cancelled.

Applicant amends claim 20-45 and argues that the foregoing amendments are now dependent on claim 1, thus group II is entitled to join group I for examination. Examiner considers the reason persuasive, therefore group I and II, claims 1-46 are joined for examination.

Applicant argues that group III should be rejoined for examination together with group I and II on the ground that group III directs subject matter closely related group I and II. Applicant's arguments have been considered but are not persuasive. The reasons are (1) the feature of "providing dual-coated two antibodies" in group I and II, is not required by the claims of group III. The feature of "providing a first antibody recognizing said free analyte and a second antibody recognizing said interfering substance when bound to said analyte" in invention III, is not required by the claims of group I and II. Thus group I-II and III are patentably distinct and independent. The restriction requirement is deemed FINAL.

Currently, claims 1-46 are under examination. Claims 47-48 are withdrawn from further consideration.

Deposit Requirement

With respect to claims 35-45, it is apparent that AMER5 and 7C2 monclonal antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the

specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded that the following and should amend the specification accordingly. The current address of the ATCC is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the preamble purports to determine the amount of an analyte in a fluid sample. However, no clear step(s) illustrating how to measure this free analyte in the test sample. Applicant recites a step "determining the total amount of said free analyte *and* said analyte bound to said interfering substance" (See step (c)). Note, this is not a free analyte determination step, rather this step merely reflects the "total" amount of free analyte and analyte bound to the interfering substance. Similarly, claim 46 suffers the same problem as in claim 1.

With respect to claim 2, line 3, "with a detectable labeled second antibody recognizing said analyte" is vague and confusing. It is not clear why this analyte recognizing antibody can be used to detect both analyte and the interfering substance bound analyte.

With respect to claim 6, line 1, "wherein said second antibody" is vague and indefinite. It is not clear whether this antibody is the labeled antibody. Similarly, claim 25 shares the same problem.

With respect to claim 6, line 3, "as well as" is vague and indefinite. It is not clear what applicant intends to recite. Positive recitation is needed. Similarly, claim 28 suffers the same problem.

With respect to claim 20, it is not clear what this claim depends from.

With respect to claim 21, line 3, "a detectable labeled second antibody" is vague and confusing. It is not clear whether this detectable antibody is the same antibody specific for the interference bound to the analyte.

With respect to claim 22, line 2, "the free antibody" lacks antecedent basis.

With respect to claim 22, line 2, "the antibody bound to said interference substance" lacks antecedent basis.

With respect to claim 22, line 2, "the antibody bound to said interference substance" is vague and confusing. It is not clear whether this antibody is a "third" kind of antibody specific only for interference. If it is, then the following steps are not consistent with claims 1-3.

With respect to claim 28, line 3, "as well as" is vague and indefinite. It is not clear what is the limitation for this phrase. Applicant needs to positively recite a claim.

With respect to claims 39, 41-43, where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular antibody detected in the instant method.

With respect to claim 41, "said second antibody against ECD is a polyclonal or monoclonal antibody" is vague and indefinite. It is not clear what characteristic this second antibody possess- specific to ECD alone or ECD bound HER2 complex, such as HER2 ECD. Similarly, claim 42 suffers the same problem.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-6, 13-21, 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Parsons et al. (US 5518887).

Parson et al. teach an immunoassay for simultaneously measuring different analytes in a tested sample. Parson et al. teach that immobilizing dual antibodies on a solid support to detect analyte and its structurally related substance, e.g. interference (Col. 5, line 1-15; line 50-65; Col. 6, line 10-28). The dual antibodies comprising a first antibody recognizing the analyte as free analyte and a second antibody recognizing said analyte interference when bound to said analyte (Col. 5, line 50-56). Parson et al. teach using this dual antibody format for detecting the presence or quantifying the amount of the target analyte in the presence of interfering substance in the test sample, e.g. determining the total amount of free analyte and interference bound to the analyte (Col. 5, line 1-15). The analytes includes, polypeptide antigen, antibodies (monoclonal or polyclonal), receptor, drug, hormone, enzymes, or erythrocyte cells (Col. 2, line 45-60; Claims 11, 13-18). The solid phases include, colloidal metals, such as gold or selenium particles, or glass fiber (Col. 6, line 49-55; Col.13, line 20-29).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 4-21, 23, 34 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (US 5518887) in view of Nishimura et al. (US 4803154).

Parsons et al. reference has been discussed but does not specifically use peroxidase or alkaline phosphatase as the detection means, e.g ELISA immunoassay. Nishimura et al. teach ELISA immunoassay by either using peroxidase or alkaline phosphatase (Col. 6, line 27-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Parson et al. with the suitable enzyme for detecting means as taught by Nishimura et al. since ELISA immunoassay for detection target molecules in a test sample is well-knonw and peroxidase as well as alkaline phosphatase are frequently used to perform in ELISA assay.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

September 11, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/17/04